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10/809,349

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Jcrome Asius

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

08/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/809,349

Applicant(s)

ASIUS ET AL.

Examiner

Paul B. Prebilit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/15/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Information Disclosure Statement

The information disclosure statement filed June 25, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The journal article to Tom et al (Biotechnology Progress) has again not been considered because a copy thereof was not in the parent file as stated in the previous Office action. And the Applicant failed to provide a copy in the response to the previous Office action.

Election/Restrictions

Newly submitted claims 20 to 22 and 28 to 30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: They are drawn to a method of making the device of a method of using the device that was not previously searched and considered.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-22 and 28-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander et al (US 5,356,629) in view of Supersaxo et al (US 5,470,582). Sander meets the claim language where the microparticles of polymers of non-animal origin are disclosed on column 3, line 48 et seq. of Sander, the hydrogel as claimed is the gel of the matrix; see column 2, lines 35-56 and the dried state is suggested by the "prior to being wetted" state; see column 3, lines 38-47. However, Sander fails to clearly disclose that the matrix is completely dry as suggested by the freeze-dried state. Supersaxo, however, teaches that it was known to freeze dry or dry similar materials in order to stabilize them for storage; see column 2, lines 19-26 and column 4, lines 40-46. Therefore, it is the Examiner's position that it would have been obvious to freeze-dry the Sander matrix for storage or for the same reasons that Supersaxo does the same.

With regard to claim 11, since the same material as claimed is disclosed by Sander, the Examiner asserts that it inherently and necessarily has the same bioresorption rate. Furthermore, it is noted that the range does not clearly have a lower limit because within about one to about three years can be interpreted as meaning the same as up to about three years.

With regard to claim 15, the Applicants are directed to column 2, lines 57-66 of Sander.

With regard to claim 16, the Applicants are directed to the paragraph bridging columns 2 and 3 of Sander.

With regard to claims 17 to 19, Supersaxo teaches the concept of including cryoprotectants and surfactants where mannitol and a surfactant is utilized; see column 4, liners 47-54. Therefore, it is the Examiner's position that it would have been obvious to utilize the same in Sander for the same reasons that Supersaxo utilizes the same.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander and Supersaxo as applied to claims 10-19 and 23 above, and further in view of Scopelianos et al (US 5,599,852). Sander as modified by Supersaxo fails to disclose the use of a kit, vial, or syringe as claimed. However, Scopelianos teaches that is was known to the art to include a kit with a syringe; see the abstract, column 1, lines 48-57, column 8, line 24 et seq., and the claims. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to utilize a kit with a syringe and vial to store the product for the long term, as suggested by Supersaxo, and to make it easier to the product.

Response to Arguments

Applicant's arguments filed June 15, 2007 have been fully considered but they are not persuasive.

The Applicant argues that Sander is directed to moldable putties, and thus, are not capable of injection. However, the Examiner asserts that putties are injected in the art as evidenced by Lee et al (US 6,287,341; see claim 3) or Scribner et al (US 2002/0099384; see paragraph [0110]. Shastri et al (US 5,837,752) teaches that it was known to adjust bone implant material viscosities to make it injectable or moldable; see column 3, lines 60-64. For this reason, the argument that the material of Sander is not

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injectable is not considered persuasive in view of the capabilities of the relevant prior art.

Additionally, the Applicant argues that Sander does not disclose microparticles or "even remotely" the particle sizes used. However, Sander clearly does require that the particles can range anywhere from 100 microns up to 3 mm in size; see column 4, lines 31-39. Therefore, the argument is considered unpersuasive in that at least the 100 micron particles are microparticles to the extent that this language can be given patentable weight.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

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Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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